

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

ABBOTT GMBH & CO., KG,)	
ABBOTT BIORESEARCH CENTER, INC.,)	C.A. No. 4:09-CV-11340 (FDS)
and ABBOTT BIOTECHNOLOGY LTD.,)	
)	
Plaintiffs,)	JURY TRIAL DEMANDED
)	
v.)	
)	
CENTOCOR ORTHO BIOTECH, INC. and)	
CENTOCOR BIOLOGICS, LLC,)	
)	
Defendants.)	

**CENTOCOR'S SUPPLEMENTAL BRIEFING ON COLLATERAL ESTOPPEL
PURSUANT TO THE COURT'S JANUARY 30, 2012 ORDER**

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I. INTRODUCTION

This is Centocor's supplemental brief responsive to the Court's January 30, 2012 Order seeking the parties' views as to the effect of the *Streck I* and *Streck II* decisions¹ on two issues:

- (1) Whether consideration of validity in an infringement action may be precluded by either (a) a prior BPAI interference decision that is subject to judicial review or (b) a contemporaneous decision of a district court in a co-pending Section 146 action; and
- (2) Whether, in a trial for concurrent infringement and Section 146 actions, resolution of validity issues by the court is consistent with *Beacon Theaters, Inc. v. Westover*, 359 U.S. 500 (1959).

(D.I. 328).

As explained below, the BPAI interference decision, which is under review in the Section 146 action, is not a final decision and thus can have no collateral estoppel effect. On the other hand, a decision of this Court in the Section 146 action could have collateral estoppel effect with respect to issues in the infringement action having common factual underpinnings with issues in the Section 146 action. The prospect that such a decision could have collateral estoppel effect raises problems under *Beacon Theaters*, which requires courts to ensure that a party's Seventh Amendment right to a jury trial of legal issues is not lost through prior determination of equitable claims other than under the "most imperative circumstances." *Beacon Theaters, Inc. v. Westover*, 359 U.S. 500, 510-511 (1959). It would thus be inconsistent with the constitutional principles of *Beacon Theaters* if the Court were to rule on issues common to the equitable and legal claims before the jury considers those common issues.

To preserve Centocor's Seventh Amendment rights, avoid potential for inconsistent fact findings by the Court and the jury, and maximize efficiency, all of the issues in the infringement

¹ *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 659 F.3d 1186 (Fed. Cir. 2011) ("*Streck I*"), and *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269 (Fed. Cir. 2012) ("*Streck II*").

action should be tried to the jury, including those issues common to the obviousness issue presented in the Section 146 Action. A bench trial on the remaining, non-common issues presented in the Section 146 Action (*i.e.*, priority of the interference count) could be scheduled, as needed, following the jury trial.

II. CONSIDERATION OF VALIDITY IN AN INFRINGEMENT ACTION MAY NOT BE PRECLUDED BY A PRIOR BPAI INTERFERENCE DECISION

As explained in Centocor’s Opposition to Abbott’s Motion for Summary Judgment No. 2 (D.I. 247, 273), the answer to the Court’s Question 1(a) – whether consideration of validity in an infringement action may be precluded by a prior BPAI interference decision that is subject to judicial review – is no. The *Streck I* and *Streck II* decisions do not alter that conclusion.

The BPAI interference decision can have no collateral estoppel effect because it is not a final and binding decision. Under Federal Circuit precedent, when Centocor undertook a “remedy by civil action” under 35 U.S.C. § 146, the result of the BPAI interference proceeding was stayed, and thus the BPAI’s decision cannot be final. *Vas-Cath, Inc. v. Curators of the Univ. of Missouri*, 473 F.3d 1376, 1382 (Fed. Cir. 2007) (citing 37 C.F.R. § 1.663). Indeed, as the Federal Circuit has stated, the civil action authorized by Section 146 to challenge a BPAI interference decision is not a new claim, but an authorized phase of the interference proceeding conducted by the Patent Office. *Id.* (citing *Rexam Indus. Corp. v. Eastman Kodak Co.*, 182 F.3d 1366, 1370 (Fed. Cir. 1999)).

A reason why the BPAI interference decision is not final and binding is that the record before this Court in the 146 Action may include evidence, including live testimony, that was not before the BPAI. *Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340, 1345 (Fed. Cir. 2000). Admission of such new evidence makes the District Court in the 146 Action a “factfinder” and “requires a *de novo* trial.” *Id.* at 1347. It is only upon completion of this Court’s determination

of the issues in the 146 Action that the patenting process will be completed. *Vas-Cath*, 473 F.3d at 1382; 37 C.F.R. § 1.661 (“After a final decision is entered by the Board, an interference is considered terminated when no appeal (35 U.S.C. 141) or other review (35 U.S.C. 146) has been taken or had.”).

This is analogous to other areas of law in which administrative decisions that are subject to *de novo* review are not given collateral estoppel effect. *See Lawson v. FMR LLC*, 724 F. Supp. 2d 141, 151-152 (D. Mass. 2010) (declining to apply collateral estoppel effect to an administrative decision because the statute expressly provided for *de novo* district court review of the decision); *Univ. of Tenn. v. Elliott*, 478 U.S. 788, 795-96 (1986) (declining to apply preclusive effect to administrative determinations in the Title VII context because Congress provided for *de novo* review of those determinations in federal court); *Nyari v. Napolitano*, 562 F.3d 916, 920-21 (8th Cir. 2009) (the district court erred in applying preclusive effect to the denial of a naturalization application because the statute requires *de novo* judicial review of the administrative decision). *See, too*, the cases indicating that a district court decision is not final where the appeal involves a trial *de novo*. *Nixon v. Ricky*, 513 F.2d 430, 438 n.75 (D.C. Cir. 1975) (“The federal rule is that pendency of an appeal does not suspend the operation of a final judgment for purposes of collateral estoppel, except where appellate review constitutes a trial *de novo*.”) (citing *Huron Corp. v. Lincoln Mine Operating Co.*, 312 U.S. 183, 188-89 (1941)).

Abbott’s argument, made at the summary judgment hearing on November 22, that the BPAI decision is final for collateral estoppel purposes because Centocor *could* have appealed it directly to the Federal Circuit under Section 141 is plainly wrong. (*See* Ex. 1, Nov. 22, 2011 Summary Judgment Motions Transcript at p. 20). The Patent Statute contemplates judicial review of a BPAI interference via the “remedy by civil action” of Section 146 utilized here.

Streck I, 659 F.3d at 1188-89. The BPAI decision cannot be final for collateral estoppel purposes if it is still under the judicial review established by statute. *Vas-Cath*, 473 F.3d at 1382.

The *Streck* decisions do not address the question of the finality of a BPAI decision and, therefore, have no bearing on the answer to the question of whether a BPAI decision subject to judicial review can have collateral estoppel effect. Rather, in the *Streck* cases, the jury verdict in the infringement action preceded the BPAI decision in the interference.

**III. A DISTRICT COURT DECISION IN A CO-PENDING SECTION 146 ACTION
MAY HAVE PRECLUSIVE EFFECT WITH RESPECT TO THE ISSUES
FINALLY DECIDED**

The answer to the Court's Question 1(b) – whether consideration of validity in an infringement action may be precluded by a contemporaneous decision of a district court in a co-pending Section 146 action – is yes, to the extent the issues are identical. In responding to this question, Centocor understands the “contemporaneous decision of the district court” to mean that there has been a trial in which the claims and defenses in the infringement action have been tried to the jury and that, based on the evidence presented, the court has ruled on issues common to the Section 146 Action.

For the purpose of discussing this question, it is assumed that Centocor would appeal a decision adverse to it in the Section 146 action. Although Centocor is not aware of a decision in which a district court decision in a Section 146 Action has been accorded collateral estoppel effect when an appeal from that ruling is pending, it acknowledges that the general rule (outside of Section 146 Actions) is that a district court decision is “final” for purposes of collateral estoppel even if an appeal from the district court decision is pending. *See, e.g., Huron Corp.*, 312 U.S. at 188-89; *In re Kane*, 254 F.3d 325, 328 (1st Cir. 2001). Assuming that a Court ruling in the Section 146 Action would thus be accorded collateral estoppel effect, it follows that, if the Court were to hold a jury trial on the claims and defenses in the infringement action here, and,

either before taking the verdict or before entering judgment on the verdict, were to decide and enter judgment on issues common to the Section 146 Action, then that judgment could preclude jury determination of the identical issues in the infringement action. And that would create the potential for serious Seventh Amendment concerns, as discussed in the next section.

As explained in the summary judgment briefing and during oral argument, priority of the artificial count (the “priority” issue in the 146 Action) and prior invention of each asserted claim (a defense in the infringement action) are *not* identical issues and do not have identical factual underpinnings. The issue of obviousness of the 128 Patent presented in the 146 Action is identical to the obviousness issue raised in the infringement action, and, as counsel acknowledged at the December 7, 2011 hearing, a prior final district court ruling on obviousness in the 146 Action could collaterally estop Centocor from subsequently presenting the same obviousness issue in the infringement action if all other conditions for collateral estoppel applied. (Ex. 2, Dec. 7, 2011 Motion Hearing Transcript, at p. 6). However, as also explained in the summary judgment briefing and during oral argument, a prior district court ruling on obviousness in the infringement action would not estop Centocor from presenting *other* invalidity defenses.

The *Streck* decisions have no bearing on the answer to Question 1(b). In the *Streck* cases, there was an identical priority issue presented in both an interference/146 Action and in an infringement action.² The order of proceedings in the *Streck* cases was:

- 1** – Jury verdict in infringement action (priority decided in favor of Streck)
- 2** – BPAI decision in interference (priority decided in favor of R&D)

² Unlike here, the parties and the district court in *Streck* agreed that the issue of priority in the 146 Action would be decided on the evidentiary record relevant to priority as adduced in the infringement trial, together with the record from the Patent Office interference proceeding. *Streck I*, 659 F.3d at 1189.

3 – District Court ruling in 146 Action (priority decided in favor of Streck)

4 – Federal Circuit decision in appeal of 146 Action (*Streck I*) (affirms)

5 – Federal Circuit decision in appeal from infringement action (*Streck II*) (affirms)

The jury verdict in the infringement action preceded both the BPAI decision in the interference and the district court ruling in the 146 Action. Accordingly, there was no “contemporaneous decision of a district court” that could be afforded collateral estoppel effect in *Streck*. See Court’s January 30, 2012 order (D.I. 328 at 2). The issue of collateral estoppel was raised, but in a different context. The *Streck II* panel referred to the *Streck I* Federal Circuit decision as having collateral estoppel effect on the issue of priority, but it did not set forth a traditional collateral estoppel analysis. Instead, it noted that R&D’s burden in the 146 action had been to prove priority by a preponderance of the evidence, and that it had failed to do so; accordingly, it could not meet the clear and convincing standard for priority required in the infringement action. *Streck II*, 665 F.3d at 1292.

IV. RESOLUTION BY THE COURT OF THE VALIDITY ISSUES PRESENTED IN THE 146 ACTION WOULD BE INCONSISTENT WITH *BEACON THEATERS*

The answer to the Court’s final question – whether, in a trial for concurrent infringement and Section 146 actions, resolution of validity issues by the court prior to the jury’s determination of common legal and factual issues is consistent with *Beacon Theaters* – is no, it would not be consistent with *Beacon Theaters* when a validity issue presents common fact issues, as does the obviousness issue here. The *Streck I* and *Streck II* decisions do not alter that conclusion.

In *Beacon Theaters*, the Supreme Court addressed the constitutionally-based importance of the order in which legal and equitable claims are to be tried. While the Court recognized that “the same court may try both legal and equitable causes in the same action,” it held that “only

under the most imperative circumstances . . . can the right to a jury trial of legal issues be lost through prior determination of equitable claims.” 359 U.S. at 508, 510-511. The Court concluded that a trial court had erred in conducting a bench trial on the equitable claim at issue, thereby precluding a jury trial on the legal claims, when the equitable claim resolved factual issues that were “common” to the legal claims.

A clear illustration of how the *Beacon Theaters* ruling has been applied in a case involving patent issues is *Shum v. Intel Corp.*, 499 F.3d 1272 (Fed. Cir. 2007). Shum alleged that defendants had misappropriated his technology and obtained a patent on it. *Id.* at 1275. He brought an action against the defendants seeking correction of inventorship of the patent and making various state law claims, including fraud, fraudulent concealment, breach of fiduciary duty, and unjust enrichment. *Id.* The court held a bench trial on the correction of inventorship issue, ruled that Shum had not proven that he was an inventor on any of the patents at issue, and then granted summary judgment on the remaining state law claims. *Id.* at 1275-76. On appeal, the Federal Circuit determined that Shum’s equitable claim for correction of inventorship shared fact issues in common with his legal claim for fraud. *Id.* at 1277. The Court ruled that, while Shum would not be entitled to a jury trial on the inventorship claim standing alone, given the co-pendency of the asserted fraud claim, a jury should have determined the facts regarding inventorship. *Id.* at 1279. The district court’s decision to try the inventorship claim before a jury trial on the state claim ran afoul of the Seventh Amendment. *Id.*

Another example is *Herman v. William Brooks Shoe Co.*, No. 95 CIV 1324, 1998 WL 832609 (S.D.N.Y. Dec. 1, 1998) (Ex. 3), a patent infringement action in which the district court had ordered a bench trial on the issue of inequitable conduct separate from a jury trial on the issues of patent validity and infringement. On a motion for reconsideration, the court reversed

course. Noting that the inequitable conduct claim had factual issues in common with the jury-triable validity claim, the court recognized that, if it were to try the inequitable conduct claim, it would be deciding the same fact issues the jury was to decide, possibly precluding the jury's consideration of those issues. *Id.* at *4. Moreover, there was also a possibility of inconsistent fact findings if the Court were to weigh the inequitable conduct issues prior to jury trial of the invalidity claim. *Id.* at *5. Given these possibilities, the court determined that preservation of the plaintiff's Seventh Amendment jury trial right dictated that a jury assess the common issues and that, following the jury trial, the court would be able to incorporate the jury's findings into its weighing of the inequitable conduct claim. *Id.*

In the instant matter, the question of the obviousness of the 128 Patent is at issue in both the 146 Action and in the infringement action. In addition, the infringement action also involves the obviousness of a second, very closely related patent, the 485 Patent. All of these obviousness issues share many common factual underpinnings, such as the level of skill of one of ordinary skill in the art, the scope and content of the prior art, motivation to combine prior art references, and possible objective indicia of nonobviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966)). If the Court were to resolve these common issues in a concurrent trial for the infringement and Section 146 actions before the issues are presented to the jury, that ruling would be inconsistent with *Beacon Theaters* because it would deprive Centocor of its right to have a jury determine its legal claims. Moreover, since, in any event, the issue of the obviousness of the closely related 485 Patent *will* be decided by the jury, there is the possibility of inconsistent fact findings if the Court also finds the common facts in the context of the obviousness issue for the 128 Patent.

To avoid the *Beacon Theaters* problem and the potential for inconsistent fact determinations, the common obviousness issues in the infringement action and the Section 146 action here should be tried concurrently, to the jury. The factual issues underlying obviousness of the 128 and 485 Patents would be appropriately resolved by the jury in the infringement action. Centocor's burden before the jury is to prove obviousness by clear and convincing evidence. If the jury ruled that Centocor met that burden with respect to the 128 Patent, and the Court entered judgment on that verdict, it would also enter judgment in Centocor's favor in the Section 146 Action because, if Centocor were to have succeeded in proving obviousness under the clear and convincing standard in the infringement action, it also would have necessarily succeeded in proving obviousness under the preponderance of evidence standard applicable in the Section 146 action. If Centocor did not meet its burden of proving obviousness under the clear and convincing standard, the district court, having heard all of the evidence while presiding over the jury trial, could then consider, in the context of the Section 146 action, whether Centocor met its burden under the preponderance of the evidence standard. Following the jury trial on the infringement action, the Court could then, as necessary, hold a bench trial on the issue that is not common to the two actions, namely, the priority-of-the-count issue presented in the Section 146 action. Trying the two cases in this way would preserve Centocor's right to a jury and would be consistent with *Beacon Theaters*.

From a discussion with Abbott's counsel, Centocor understands that Abbott contends that, under the reasoning of *Parklane Hosiery Co. v. Shore*, 439 U.S. 322 (1979), there would be no Seventh Amendment problem with trying and/or deciding the 146 Action prior to the infringement action because the two actions are different and arise from different backgrounds. But *Parklane* does not stand for the proposition that a jury right can be lost simply because

related claims are presented in separate actions. *Parklane* involved one lawsuit filed by shareholders against the defendants and a second (equitable) action filed by the SEC against the defendants. 439 U.S. at 324-25. Before the shareholder suit even came to trial, a district court had entered a declaratory judgment in the SEC action, and the Second Circuit had affirmed that judgment. *Id.* at 325. Unlike here, the two cases were not co-pending before the same judge, and the defendants “made no effort to protect their right to a jury trial” by seeking an expedited trial of the legal claims before a decision on the equitable claims, nor by requesting that the same judge hear both cases. *Id.* at 337 n.24. By contrast, here, the 146 Action and the infringement action were filed at the same time, involve the same parties, are before the same judge, and were consolidated for discovery. This court can readily schedule trial so that legal issues can be tried to and decided by a jury. There are no “imperative circumstances” that would justify the loss of the right to a jury trial of legal issues. *Beacon Theaters*, 359 U.S. at 510-11 (“[E]quity dictates that only under the most imperative circumstances . . . can the right to a jury trial of legal issues be lost through prior determination of equitable claims.”).

Moreover, although the facts in *Beacon Theaters* involved legal and equitable claims in a single action, the Court’s reasoning was not limited to that situation. It expressly recognized that, even in a situation where legal and equitable causes could not be joined in one suit, a court has limited discretion to decide the causes in a way that would deprive a legal claimant of a jury trial:

If there should be cases where the availability of declaratory judgment or joinder in one suit of legal and equitable causes would not in all respects protect the plaintiff seeking equitable relief from irreparable harm while affording a jury trial in the legal cause, the trial court will necessarily have to use its discretion in deciding whether the legal or equitable cause should be tried first. Since the right to jury trial is a constitutional one, however, while no similar requirement protects trials by the court, that discretion is very narrowly limited and must, wherever possible, be exercised to preserve jury trial.

Id. at 510 (emphasis added).

Indeed, other courts have rejected Abbott's notion that *Beacon Theaters* is limited to claims presented in a single lawsuit. For example, in *Cedars-Sinai Medical Center v. Revlon, Inc.*, 111 F.R.D. 24, 31 (D. Del. 1986), there were two related patent infringement cases, involving different but "closely related" patents. No timely jury demand was made in the first case, but a timely demand was made in the second. *Id.* Citing *Beacon Theaters*, the court ruled, based on Seventh Amendment and collateral estoppel concerns, that the two cases should be consolidated for trial before a single jury. *Id.* at 32. Even though the two suits involved different patents, the court found that there were a number of issues common to the two cases. For example, it noted that much of the prior art would be the same for the two patents.³ *Id.* at 33. The court concluded that "the high probability of collateral estoppel in this case, at least on the issues of validity, infringement, and enforceability, favors consolidation of the two cases before a single jury. A court must make every effort to ensure that a party's right to trial by jury is not weakened or eliminated altogether by a prior determination of common issues in a non-jury trial, by collateral estoppel." *Id.* (citations omitted). The court further explained that "[a] possible alternative, of course, would be to try [the second action] first, where the jury trial is of right, then have the Court try [the first action]. Although estoppel would occur, it would not directly infringe on the plaintiff's constitutional right to a jury trial. However, when one of the cases is a jury trial, and common issues of law and fact exist, a single jury should be the same trier of fact."

Id.

³ This is similar to the instant case, where the infringement suit involves the issue of obviousness of a second patent, the 485 Patent, not in issue in the 146 Action, but for which the underlying factual issues, such as the scope and content of the prior art, are greatly overlapping.

The *Streck* decisions do not affect the answer to Question 2. The common issues in the 146 Action and in the infringement suit were tried to a jury first. There was no question of an earlier ruling on equitable issues eliminating the right to a jury on fact issues.

V. COMMENT ON TRIAL TIMING AND TIME

Centocor appreciates, from the nature of the questions posed by the Court's January 30, 2012 Order (D.I. 328), that the Court is considering how, and in what order, to try the 146 Action and the jury trial in the infringement action. The parties have previously discussed with the Court the possibility of a five week trial (from September 10 to October 12, 2012) (*see* Ex. 1, Nov. 22, 2011 Summary Judgment Motions Transcript at p. 154), and Centocor does wish to make note of its contention that a jury trial on all of the claims and defenses in the infringement action will take five weeks, given the complexity of the technology and the issues, the number of patent claims in issue (two patents, 47 claims), and the number of witnesses (e.g., Abbott alone submitted reports from ten experts). This five week estimate assumes equal time allotted to Plaintiff and Defendant and would not include trial of the separate priority-of-the-count issue in the Section 146 action.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing CENTOCOR'S SUPPLEMENTAL BRIEFING ON COLLATERAL ESTOPPEL PURSUANT TO THE COURT'S JANUARY 30, 2012 ORDER was electronically mailed to counsel of record on February 13, 2012 through the Court's ECF notification system.

/s/ Angela Verrecchio